

a top and a bottom dressing, both being formed from a flexible material and having upper and lower surfaces, the lower surfaces being skin facing when the dressing in use;

the bottom dressing having a slit formed therein extending from one edge inwardly to a termination point within the confines of the bottom dressing;

an anti-microbial material provided without the use of adhesives at the upper and lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing;

whereby, in use, the bottom dressing is placed next to the skin, the slit allowing the bottom dressing to surround the puncture site such that the lower surface of the bottom dressing is in contact with the skin and the upper surface of the bottom dressing is in contact with a portion of the medical device protruding from the skin, and the top dressing is placed above the puncture site such that its lower surface is in contact with a portion of the medical device protruding from the skin, thereby exposing a portion of the medical device protruding from the skin from above and below to the anti-microbial activity of the anti-microbial material.

28. 2 The dressing as set forth in claim *27*, wherein:

the top and bottom dressings are formed from a unitary dressing and are joined together and divided by a fold line.

29. 3 The dressing as set forth in claim *28*, wherein:

the anti-microbial material is a coating of an anti-microbial metal applied to the upper and lower surfaces of the bottom dressing, and at least to the lower surface of the top dressing.

30. 4 The dressing as set forth in claim *29*, wherein the slit is formed from the edge of the bottom dressing which is parallel to the fold line, such that the slit is generally perpendicular to the fold line.

31. 5 The dressing as set forth in claim *30*, wherein the top and bottom dressings are formed from multilayered, laminated dressing materials.

32. 6 The dressing as set forth in claim *31*, wherein the top and bottom dressings are formed from:

a first, skin facing layer formed of a perforated, non-adherent material; a second layer laminated to the first layer, and being formed of an absorbent material; and a third layer laminated to one or both of the first and second layers.

36.7 The dressing as set forth in claim *36.6*, wherein the anti-microbial metal coating is formed on the first and the third layers.

36.8 The dressing as set forth in claim *36.7*, wherein the top and bottom dressings are sized so as to provide coverage of the portion of the medical device protruding from the skin of at least about 5 mm.

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36.9 The dressing as set forth in claim *36.8*, wherein the anti-microbial metal coating is a thin film containing at least one anti-microbial metal, said anti-microbial metal being formed with sufficient atomic disorder such that the thin film, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-microbial effect on a sustainable basis.

36.10 The dressing as set forth in claim *36.9*, wherein the anti-microbial metal coating comprises:

a base layer of a partly reflective material capable of generating an interference colour when covered with a partly reflective, partly light transmissive top layer;

a top layer formed over said base layer, said top layer being a partly reflective, partly light transmissive thin film containing at least one anti-microbial metal and having a thickness such that a first or second order interference colour is produced, said top layer having a refractive index different from that of the base layer, and anti-microbial metal being formed with sufficient atomic disorder such that the top layer, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-microbial effect on a sustainable basis.

36.12 The dressing as set forth in claim *36.10*, wherein the material in the base layer is a metal selected from the group consisting of Ag, Au, Pt, Pd, Cu, Ta, Al and alloys or compounds of one or more of these metals, in a partly reflective form, and wherein the anti-microbial metal in the top layer is selected from the group consisting of Ag, Au, Pt, Pd, Ir, Sn, Cu, Sb, Bi, Zn, and alloys or compounds of one or more of these metals.

36.13 The dressing as set forth in claim *36.12*, wherein the material in the base layer and the anti-microbial metal in the top layer is a metal selected from the group consisting of Au, Ag, Pt, Pd, and Cu in a partly reflective form, and is formed by vapour deposition with sufficient atomic

disorder such that the top layer, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-microbial effect on a sustainable basis.

38.14 The dressing of claim 38, wherein the metal in the base and top layer is Ag, Pt or Au.

40.11 The dressing as set forth in claim 38, wherein the top layer is a thin film of a composite material formed by co-, sequentially or reactively depositing the anti-microbial metal by vapour deposition in a matrix with atoms or molecules of a different material to create atomic disorder in the matrix, said different material being selected from the group consisting of biocompatible metals, oxygen, nitrogen, hydrogen, boron, sulphur or halogens, or an oxide, nitride, carbide, boride, halide, sulphide or hydride of either or both of an anti-microbial metal or a biocompatible metal.

41.16 The dressing as set forth in claim 40, wherein the biocompatible metal is selected from the group consisting of Ta, Ti, Nb, V, Hf, Zn, Mo, Si and Al.

42.17 The dressing as set forth in claim 41, wherein the anti-microbial metal is silver and said different material is one or both of silver oxide and atoms or molecules containing oxygen trapped or absorbed in the matrix.

43.18 The dressing as set forth in claim 42, wherein the top layer is less than 400 nm thick, and the base layer is at least 25 nm thick.

44.19 The dressing as set forth in claim 43, wherein the top layer is between 5 and 210 nm thick, and the base layer is at least 60 nm thick.

45.20 The dressing as set forth in claim 44, wherein the top layer is about 40 - 160 nm thick and the base layer is at least about 300 nm thick.

46.21 The dressing as set forth in claim 38, wherein the first and third layers are formed from a non-woven, perforated, non-adherent high density polyethylene material.

47.21 The dressing as set forth in claim 46, wherein the first and third layers are formed from a non-woven, perforated, non-adherent high density polyethylene material.

48.22 The dressing as set forth in claim 47, wherein the second layer is formed from a non-woven, absorbent rayon/polyester material.

40.23 A method of dressing the puncture site of a transcutaneous medical device to limit infection by microorganisms from the surrounding skin and a portion of the medical device that protrudes from the skin of a patient, comprising:

providing a transcutaneous device dressing, comprising:

a top and a bottom dressing, both being formed from a flexible material and having upper and lower surfaces, the lower surfaces being skin facing when the dressing is in use;

the bottom dressing having a slit formed therein extending from one edge inwardly to a termination point within the confines of the bottom dressing; and

B3 an anti-microbial material provided without the use of adhesives at the upper and lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing;

sliding the bottom dressing in place next to the skin using the slit to allow the bottom dressing to surround the puncture site at the termination point such that the lower surface of the bottom dressing is in contact with the skin surrounding the puncture site and the upper surface of the bottom dressing is in contact with a portion of the medical device protruding from the skin;

applying the top dressing above bottom dressing such that the lower surface of the top dressing is in contact with a portion of the medical device protruding from the skin;

depending on the anti-microbial material, applying a water or alcohol based electrolyte to the dressing to release the anti-microbial material; and

fixing the top and bottom dressings to the skin.

50.14 The method as set forth in claim *40.23*, wherein:

the top and bottom dressings are formed from a unitary dressing and are joined together and divided by a fold line.

50.11 The method as set forth in claim *50.14*, wherein:

the anti-microbial material is a coating of an anti-microbial metal applied to the upper and lower surfaces of the bottom dressing, and at least to the lower surface of the top dressing.

50.24 The method as set forth in claim *50.14*, wherein the slit is formed from the edge of the bottom dressing which is parallel to the fold line, such that the slit is generally perpendicular to the fold line.

50.27 The method as set forth in claim *50.24*, wherein the top and bottom dressings are formed from multilayered, laminated dressing materials.

54.28 The method as set forth in claim *58*, wherein the top and bottom dressings are formed from:

- a first, skin facing layer formed of a perforated, non-adherent material;
- a second layer laminated to the first layer, and being formed of an absorbent material; and
- a third layer laminated to one or both of the first and second layers.

58.29 The dressing or method as set forth in claim *54*, wherein the anti-microbial metal coating is formed on the first and the third layers.

58.30 The method as set forth in claim *58*, wherein the top and bottom dressings are sized so as to provide coverage of the portion of the medical device protruding from the skin of at least about 5 mm.

58.31 The method as set forth in claim *58*, wherein the anti-microbial metal coating is a thin film containing at least one anti-microbial metal, said anti-microbial metal being formed with sufficient atomic disorder such that the thin film, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-microbial effect on a sustainable basis.

58.32 The method as set forth in claim *58*, wherein the anti-microbial metal coating comprises:
a base layer of a partly reflective material capable of generating an interference colour when covered with a partly reflective, partly light transmissive top layer;

a top layer formed over said base layer, said top layer being a partly reflective, partly light transmissive thin film containing at least one anti-microbial metal and having a thickness such that a first or second order interference colour is produced, said top layer having a refractive index different from that of the base layer, and anti-microbial metal being formed with sufficient atomic disorder such that the top layer, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-microbial effect on a sustainable basis.

59.33 The method as set forth in claim *58*, wherein the material in the base layer is a metal selected from the group consisting of Ag, Au, Pt, Pd, Cu, Ta, Al and alloys or compounds of one or more of these metals, in a partly reflective form, and wherein the anti-microbial metal in the

top layer is selected from the group consisting of Ag, Au, Pt, Pd, Ir, Sn, Cu, Sb, Bi, Zn, and alloys or compounds of one or more of these metals.

60.³⁴ The method as set forth in claim 59, wherein the material in the base layer and the anti-microbial metal in the top layer is a metal selected from the group consisting of Au, Ag, Pt, Pd, and Cu in a partly reflective form, and is formed by vapour deposition with sufficient atomic disorder such that the top layer, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-microbial effect on a sustainable basis.

61.³⁵ The method of claim 60, wherein the metal in the base and top layer is Ag, Pt or Au.

62.³⁶ The method as set forth in claim 61, wherein the top layer is a thin film of a composite material formed by co-, sequentially or reactively depositing the anti-microbial metal by vapour deposition in a matrix with atoms or molecules of a different material to create atomic disorder in the matrix, said different material being selected from the group consisting of biocompatible metals, oxygen, nitrogen, hydrogen, boron, sulphur or halogens, or an oxide, nitride, carbide, boride, halide, sulphide or hydride of either or both of an anti-microbial metal or a biocompatible metal.

63.³⁷ The method as set forth in claim 62, wherein the biocompatible metal is selected from the group consisting of Ta, Ti, Nb, V, Hf, Zn, Mo, Si and Al.

64.³⁸ The method as set forth in claim 63, wherein the anti-microbial metal is silver and said different material is one or both of silver oxide and atoms or molecules containing oxygen trapped or absorbed in the matrix.

65.³⁹ The method as set forth in claim 64, wherein the top layer is less than 400 nm thick, and the base layer is at least 25 nm thick.

66.⁴⁰ The method as set forth in claim 65, wherein the top layer is between 5 and 210 nm thick, and the base layer is at least 60 nm thick.

67.⁴¹ The method as set forth in claim 66, wherein the top layer is about 40 - 160 nm thick and the base layer is at least about 300 nm thick.

68.⁴² The method as set forth in claim 57, wherein the first and third layers are formed from a non-woven, perforated, non-adherent high density polyethylene material.